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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,126	03/17/2004	James Robert Schwartz	9183M&	4865

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EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,126	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/28/05</u> <u>09/20/05</u> <u>1/27/05</u> <u>11/15/2005</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/803,126 filed on 03/17/2004. Claims 1-25 are pending and are accordingly presented for examination on the merits.

Claim Objections

Claim 19 is objected to because of the following informalities: The part: 'and wherein said zinc hydroxide' is recited twice. Appropriate correction is required. The Examiner suggests that the first appearance of the phrase be deleted.

Applicant is also suggested to change 'ZPT' in instant claims 2 and 3 to zinc pyrithione for purposes of clarity.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner what constitutes an 'effective amount' of zinc-containing layered material and an 'effective amount' of a pyrithione or

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polyvalent metal salt of pyrithione when the claims are drawn to a composition without an intended use. The Examiner interprets the claims to read upon a composition comprising the ingredients.

Claims 1-14 and 23-25 are also rejected as being indefinite because they are dependent on an indefinite base claim.

Claim Rejections - 35 USC § 112

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10-14 are drawn to a composition according to claim 1 wherein the zinc-containing layered material is present from about 0.001% to about 10%. It is unclear to the Examiner the exact meaning of the range. The numbers should be followed by, for example, mol percent, weight percent, etc... For purposes of examination, the Examiner will interpret the claims as it reads on weight percent of the composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151).

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt, such as zinc carbonate, and an anionic deterative surfactant for a topical carrier thus reading on instant claims 1-3, and 15-17 (Claims 1 and 6). The zinc salt can be the insoluble particulate zinc carbonate anticipating instant claims 5-8 (Claim 6). Please note that the Examiner interprets zinc carbonate to be synonymous with basic zinc carbonate as defined in the instant specification (Page 4, lines 11-34; and page 5, lines 16-18). The zinc-containing layered material (zinc carbonate) is present from 0.001% to 10% by weight of the composition preferably 0.1% to 2% by weight and in a ratio of to the antimicrobial active agent (zinc pyrithione) from about 5:100 to about 5:1 (claim 1). Please note that since the composition is the same and in the same proportions as the instantly claimed invention, then the composition of Gavin et al. would inherently have an augmentation factor of greater than 1. The Patent and Trademark Office is not equipped with the scientific equipment to compare the composition of Gavin et al. to the instantly claimed invention but when the compositions are comprised of the exact same materials and would inherently have the exact same properties then the burden is appropriately shifted to the Applicant to demonstrate unexpected results otherwise.

Gavin et al. disclose zinc pyrithione as a preferred metal salt of pyrithione thus reading on instant claim 9 (claim 1). Gavin et al. disclose a range of 0.001 to 10%; 0.1 to 2% and 0.01 to 5% by weight of the composition of the metal ion source (i.e., zinc

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carbonate) which reads on instant claim 10 and anticipates the ranges of 0.01 to about 7% in instant claim 11 and 0.1% to 5% of instant claim 12 (claims 1, 5 and 6). Gavin et al. disclose the zinc pyrithione as being 0.001% to 10% and preferably 0.1% to 2% by weight of the composition in claim 1 and disclose a range of 0.1 to 5% by weight of the composition in claim 2 and thus anticipating the ranges of instant claims 13 and 14.

Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Claim Rejections - 35 USC § 102

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Biener (US 4,943,432).

Claim 22 is drawn to a process for preparing a basic zinc carbonate-containing personal care composition comprising reacting a carbonate or bicarbonate salt with a zinc compound to form in-situ the basic zinc carbonate.

Biener discloses a composition for the treatment of psoriasis and other skin diseases comprising zinc chloride (a zinc salt of an inorganic acid) and sodium carbonate (Abstract; Column 4, lines 47-48 and claim 8, for example). Biener discloses the treatment of hundreds of patients by bathing in solutions of the salt mixtures or application of the mixtures to the skin (Column 3, lines 13-23). Thus, solutions comprising the zinc salt and the sodium salt would have inherently reacted in the

mixture and produced basic zinc carbonate in-situ thus reading on the process of instant claim 22.

Claim Rejections - 35 USC § 102

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Cilley et al. (US 4,933,101).

Cilley et al. disclose a detergent composition comprising sodium carbonate and zinc oxide (Column 22, lines 1-23). Cilley et al. provide methods of making the composition, which comprises paddling the zinc oxide into a pre-mixed sodium carbonate containing mixture (Column 22, lines 25-44). Since the components are the same in the Cilley et al. disclosure as the instantly claimed composition then it would have formed basic zinc carbonate in-situ and anticipate the instant invention.

Please note: With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, a personal care composition, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the

same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman (US 4,161,526) in view of Daley (US 3,960,782).

Gorman discloses a skin cleansing composition comprising zinc pyrithione, water, an alcohol and zinc oxide (Column 2, lines 23-51). Gorman discloses a method to make the composition where the additional zinc component was added to the zinc pyrithione/water/alcohol composition and the result produced a much better looking product (Column 2, lines 41-51). Zinc hydroxide may be used in the composition (Column 2, lines 7-9 and claims 1 and 4).

Gorman does not expressly disclose the addition of a bicarbonate/carbonate salt to the composition that would react in-situ with the zinc salt to produce basic zinc carbonate within a range of between about 1:10 and about 10:1.

Daley et al. provide a general teaching of conventional ingredients in the formulation of shampoos (Column 3, lines 17-19). Daley et al. disclose that sodium

carbonate is a suitable pH-adjusting agent and zinc pyridinethiol-N-oxide is a suitable anti-dandruff agent (Column 3, lines 23-27).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Gorman by adding sodium carbonate as suggested by Daley et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Daley et al. disclose that sodium carbonate is a conventional pH adjusting reagent in shampoo compositions. The adjustment of particular working conditions, (i.e., the ratio of carbonate salt to zinc salt), is deemed merely a matter of routine optimization of conventional working conditions, which is well within the purview of one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1, 8, 9, 13, 14 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, 12, 38-42 and 51-53 of copending Application No. 10/742,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the claims in the copending application as set forth in the claims analysis table below.

Instant Application 10/803,126	Common claim elements	Copending Application 10/742,557 (12/19/2003)
1	Pyrrithione or metal salt of pyrrithione and a zinc-containing material	1, 11, 12 and 38
9	Zinc pyrrithione	39
8	Basic zinc carbonate	40
13	0.01 to about 5% zinc pyrrithione	41
14	0.1 to about 2% zinc pyrrithione	42
23-25	Method of treating microbial infections, fungal infections and dandruff	51-53

One of ordinary skill in the art would have recognized that the compositions have the same components in the same ratios and would have the same augmentation factor. The selection of the size of the particulate zinc material (i.e., a crystallite size of less than about 600 angstroms) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art. The comprising language of the instant application does not preclude a crystallite size of less than about 600 angstroms. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

II. Claims 1, 5-9, 13 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 14-17 and 23-24 of copending Application No. 10/802,166. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application as is shown in the claims analysis table below.

Instant Application 10/803,126	Common claim elements	Copending Application 10/802,166 (03/17/2004)
1	Zinc-containing layered material; metal salt of pyrrhione	1 and 2
1 and 5	Zinc-containing material is basic zinc carbonate	1, 2 and 14
1 and 6	Zinc-containing material is basic zinc carbonate	1, 2 and 15
1 and 7	Zinc-containing material is basic zinc carbonate	1, 2 and 16
1 and 8	Zinc-containing material is basic zinc carbonate	1, 2 and 17

Instant Application 10/803,126	Common claim elements	Copending Application 10/802,166 (03/17/2004)
1 and 9	Zinc pyrithione	1-3
1, 9 and 13	0.01 to 5% zinc pyrithione	1-3 and 5
1, 2 and 23	Method of treating microbial infections	1 and 23
1, 2 and 24	Method of treating fungal infections	1 and 24
1, 2 and 25	Method of treating dandruff	1 and 25

One of ordinary skill in the art would have recognized that the composition comprising a zinc-containing layered material; a surfactant; and a metal salt of pyrithione is encompassed by the composition of the co-pending application comprising a metal salt of pyrithione and a zinc-containing layered material. Since the compositions are the same then the compositions are would inherently have the same characteristics including lability of the zinc. The addition of anionic surfactants to zinc pyrithione dandruff shampoos has been suggested by Bowser et al. (US 5,723,112) (Abstract; column 3, lines 19-41 and claims 1-8, for example). The selection of surfactants (i.e., surfactants with anionic functional groups) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art. The comprising language of the instant invention does not preclude the addition of surfactants with anionic functional groups. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

III. Claims 1, 5-8, 13 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9, 18-21 and 26-28 of copending Application No. 11/100,648. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass or are encompassed by the claims of the copending application as set forth in the claims analysis table below.

Instant Application 10/803,126	Common claim elements	Copending Application 11/100648 (04/07/2005)
1	Zinc containing layered material; pyrithione or metal salt of pyrithione	1 and 2
9	Zinc pyrithione	3
5	Zinc containing layered material	18
6	Zinc containing layered material	19
7	Hydrozincite or basic zinc carbonate	20
8	Basic zinc carbonate	21
13	0.01% to about 5% zinc pyrithione	9
23-25	Method of treating microbial infections; treating fungal infections; treating dandruff	26-28

One of ordinary skill in the art would have recognized the obvious variation of the instantly claimed invention as set forth in the claims analysis table above. Since the compositions are the same then the compositions are would inherently have the same characteristics including augmentation factor. The comprising language of the instant invention does not preclude the addition of surfactants with anionic functional groups,

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cationic polymers, a relative zinc lability and pH greater than 6.8. The addition of anionic surfactants and cationic polymers to zinc pyrithione dandruff shampoos has been suggested by Bowser et al. (US 5,723,112) (Abstract; column 3, lines 19-41, column 4, lines 62-67; column 5, lines 1-30 and claims 1-8, for example). The selection of surfactants and polymers and adjustment of zinc lability and pH is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

IV. Claims 1, 5-9, 13, and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7, 18-21 and 30-32 of copending Application No. 11/216,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application embrace or are embraced by the claims of the copending application as set forth in the claims analysis table below.

Instant Application 10/803,126	Common claim elements	Copending Application 11/216,520 (08/31/2005)
1	Pyrithione or metal salt of pyrithione; zinc containing material	1 and 2
5	Zinc containing material	18
6	Basic zinc carbonate; hydrozincite; zinc carbonate hydroxide	19
7	Hydrozincite or basic zinc carbonate	20
8	Basic zinc carbonate	21

Instant Application 10/803,126	Common claim elements	Copending Application 11/216,520 (08/31/2005)
9	Zinc pyrithione	3
13	0.01% to about 5% zinc pyrithione	7
23-25	Method of treating microbial infections; treating fungal infections; treating dandruff	30-32

One of ordinary skill in the art would have recognized the obvious variation of the instant invention in the copending application. Since the compositions are the same then the compositions are would inherently have the same characteristics including augmentation factor and zinc lability. The comprising language of the instant invention does not preclude the addition of surfactants with anionic functional groups and zinc binding materials. The addition of anionic surfactants to zinc pyrithione dandruff shampoos has been suggested by Bowser et al. (US 5,723,112) (Abstract; column 3, lines 19-41 and claims 1-8, for example). Bowser et al. suggests the addition of buffering or pH adjusting agents (Column 6, line 29) and suitable pH adjusting agents known in the art include citric acid as suggested by Cardin et al. (US 5,104,645) (column 10, lines 55-56). The specification of 11/216,520 points out that citric acid can be a zinc binding material (page 11, lines 3-6). The selection of surfactants and zinc binding materials and is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

V. Claims 1, 8, 9 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of U.S. Patent No. 6,908,912. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of the instant invention, pyrithione or a polyvalent metal salt of a pyrithione and a zinc-containing layered material is embraced by the claims of the patent. The patent claims are drawn to an antimicrobial composition comprising pyrithione or a pyrithione complex and a zinc source in an amount of from 0.01% to 5% by weight of the composition (Claim 1). The pyrithione salt can be zinc pyrithione (Claim 3). Zinc carbonate can be the source of zinc ion (Claim 5).

One of ordinary skill in the art would have recognized the obvious variation of the instant invention in the patented claims as discussed above. Since the compositions are the same then the compositions are would inherently have the same characteristics including augmentation factor. The comprising language of the instant invention does not preclude the addition of amines from the composition. The selection of amines for addition to the composition is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA



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